Exhibit 9 [replacing Dkt. #2225-9] attached to Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude Seth Whitelaw's Opinions and Proposed Testimony at Dkt. #2221.

- Redactions withdrawn by Defendant

PD6 Exh 9

McKesson Internal Audit

MCKESSON
Empowering Healthcare

Audit Report

Controlled Substance Monitoring Program

US Pharmaceutical

To: Ina Trugman, Attorney

From: Internal Audit Department

Subject: Controlled Substance Monitoring Program

	Current Audit	Prior Audit
Date Audit Completed:	August 25, 2008	N/A
Audit Report Date:	October 8, 2008	N/A
Report Reference Number:	09-SSPH-04	N/A
Rating:	Yellow – Needs Improvement	N/A
Copies To:	See Distribution List	

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Executive Summary

Background

McKesson US Pharmaceutical Distribution is responsible for ensuring the Distribution Center (DC) network is in compliance with an agreement entered into on May 2, 2008, with the U.S. Drug Enforcement Administration (DEA). This agreement requires that McKesson establish a compliance program designed to detect and prevent diversion as required under the Controlled Substances Act and applicable DEA regulations. The agreement also provides for inspections by the DEA between 90 and 150 days following the May 10, 2008, effective date.

McKesson implemented the Controlled Substance Monitoring Program (CSMP) in June 2008 to detect and prevent the diversion of controlled substances and satisfy the control and reporting requirements of the agreement. It is important to note, however, that the CSMP policies, procedures, and controls are not in themselves requirements of the DEA agreement or of law. As a result, any issues identified in this report should not be interpreted as failures to comply with the requirements of the agreement, or of any law or regulation.

The SAP system supports the program by blocking orders, pending review, that exceed thresholds at DCs. SAP also currently blocks orders of hydrocodone or alprazolam to non-government accounts at the Conroe and Lakeland DCs, as required by the temporary suspension that is part of the DEA agreement. Early in the CSMP implementation, the Conroe DC inadvertently shipped discontinued products containing hydrocodone because they had not been clearly identified as products subject to the temporary suspension. Management implemented signage within the Conroe and Lakeland DCs to alert employees that products containing alprazolam or hydrocodone should not be picked (except for the federal government accounts which are listed on the signs).

As noted above, the DEA agreement included a 90 day "ramp-up" period before the CSMP would be subject to government inspection. In order to ensure that the CSMP would be fully operational in time to satisfy the Company's obligations under the DEA agreement, the Law Department requested that Internal Audit perform an interim assessment of the CSMP implementation. Planning for that assessment began in June and fieldwork started in late July, in time to make any necessary adjustments prior to the inspections by the DEA.

Scope and Objectives

Our review evaluated the effectiveness of CSMP policies, procedures, and controls. We also reviewed the general and automated application controls within the SAP and ACUMAX systems, which are instrumental in CSMP compliance and monitoring. Our scope was limited to US Pharma DC operations, including shipments by US Pharma to McKesson Medical-Surgical (Med-Surg) customers. We did not review other business units that may ship controlled substances to customers, such as Med-Surg, McKesson Specialty, and McKesson Canada. Management has prioritized obtaining CSMP documentation for Independent, Small and Medium Chain (ISMC) customers due to the elevated risk of controlled substance diversion in that segment. However, our scope included a review of all customer files to identify areas for improvement.

From a Distribution Center network of 31 locations, Internal Audit selected five DCs for detailed testing: Conroe, Texas; Lakeland, Florida; Landover, Maryland; Livonia, Michigan; and Southern

California. The first three were selected because the DEA will visit them later this year. The other two sites were chosen based on the controlled substance volume and dollars passing through that DC. We also ensured that at least one DC from each region was selected.

The DEA reporting as specified in the agreement is in the process of being developed by the Pharma DC Management and the DEA and, as such, was not examined as part of our review.

Our primary audit objectives were as follows:

- Evaluate key policies and procedures integral to the CSMP process;
- Evaluate the effectiveness of the processes surrounding the set-up of new and existing customer files and thresholds for the CSMP;
- Evaluate the effectiveness of key processes surrounding the monitoring of the CSMP; and
- Ensure that adequate system controls have been implemented to establish and monitor established controlled substance thresholds.

Overall Conclusion

Rating – Yellow – Needs Improvement

Based on the testing performed to meet our audit objectives, we concluded that the distribution centers had yet not fully implemented the Standard Operating Procedures as adopted June 24, 2008 by management. The issues identified were communicated to management and are summarized below. Management has reported that all issues have been addressed as of the issuance of this report.

Key Issues

The following represent the significant issues identified during the audit in July and August 2008:

- Customers Without Thresholds
  - Approximately 1000 Med-Surg customers who receive shipments from the Lakeland Pharma DC, and 359 Pharma customers served by various DCs, are assigned a threshold value of No Allocation (NOAL), allowing unlimited dosages of controlled substances to be ordered and shipped. For hydrocodone and alprazolam, the shipping blocks at Lakeland override NOAL thresholds.

- Threshold Excursion and Change Documentation
  - Threshold excursion reviews and threshold changes are not consistently performed and documented as required per the Standard Operating Procedures (SOP) in place.

- Standard Operating Procedure Modifications
  - CSMP SOPs do not always provide clear and consistent guidance for initiating and monitoring established controlled substance thresholds.

- Supporting Documentation for Existing and New Customers
  - Completed sales questionnaires (the minimum documentation required in the SOP) are not consistently created and retained for either new or existing customers.

- Documentation for Medical-Surgical Customers
  - Documentation and due diligence for Med-Surg customers whose controlled substance orders are shipped from the US Pharma Lakeland DC have not been created and retained in compliance with the Controlled Substance Monitoring Program SOPs.

A detailed report of all issues has been documented in the attached table.

Audit Committee Summary

We audited new processes as they were being rolled out to the US Pharma Distribution Center network to manage the Controlled Substance Monitoring Program (CSMP). McKesson's agreement with the DEA requires that a compliance program exists to detect and prevent diversion of controlled substances. We also evaluated system controls that establish and monitor controlled substance thresholds.

We noted the following key issues:

- Some Med-Surg and Pharma customers had not yet been assigned thresholds in the system to flag large shipments of controlled substances for review.
- Documentation evidencing new customer due diligence was incomplete. In addition, documentation supporting the company's decision to change thresholds for existing customers was also incomplete.
- We also identified opportunities to enhance and clarify the Standard Operating Procedures (SOPs).

Management has begun to modify the SOPs and is reinforcing the procedures required under CSMP. All of the items noted have already been addressed by management.

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
1	**Customers Without Thresholds** Approximately 1000 Medical Surgical Solutions (Med-Surg) and 359 Pharma customers are assigned a threshold value of NOAL, allowing unlimited amounts of controlled substances to be ordered and shipped. For hydrocodone and alprazolam, the shipping blocks at Lakeland override NOAL thresholds.	**Significance**: High **Risk:** Lack of established thresholds may impede identification of large purchases of controlled substances.	Recommendation Management is in the process of reviewing and updating the threshold records.	Keith McIntyre	Completed on 8/25/08
2	**Threshold Excursion and Change Documentation** Threshold excursion reviews and threshold changes are not consistently performed and documented as required per CSMP SOPs. • A review of 125 threshold excursions at five DCs identified the following exceptions: ○ Eighty-nine of the 100 excursions reviewed at four DCs did not contain documented evidence that a Level I review by DC management had been performed. In Lakeland,, three of the Level 1 reviews were also not performed timely (within one week of the excursion). ○ Additionally, for 74 threshold excursions that resulted in blocked customer orders at the four DCs reviewed, documentation could not be provided to evidence that 71 of the blocked orders had been communicated tc the customer as required per the SOP. ○ Threshold excursions were not reviewed at one DC because the	**Significance:** High **Risk:** The company may be unable to monitor compliance with the review requirements of the CSMP or demonstrate such compliance upon audit.	Recommendation: Management should document all Level I reviews performed and place the documentation, along with the decision regarding the threshold change request and the research performed to support the decision, in the customer file. Threshold Change Forms should be completed for all threshold changes that are processed and should be approved and retained in the customer file.	Don Walker	Completed on 8/25/08

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	SOP had not been fully implemented. The Distribution Center Manager (DCM) indicated that he had only performed one Level 1 review and confirmed that blocked orders had not been communicated to the customer since CSMP was implemented. • A review of 119 threshold changes at five DCs identified the following exceptions: ○ No documentation of the threshold change request, approvals, or the rationale for the change was on file for 60 of the changes reviewed. ○ Twelve of the threshold changes were not documented on a Threshold Change Form (approvals and rationale for the change were on file). ○ Three of the threshold changes were not formally approved by the Director of Regulatory Affairs (DRA). ○ Appropriate supporting documentation for the threshold change was either not obtained or not obtained timely by management for five of the threshold changes reviewed.				
3	**Standard Operating Procedure Modifications** CSMP SOPs do not always provide clear and consistent	**Significance:** High **Risk:** CSMP SOPs do not	Recommendation: Management should modify policies and	Tracy Jonas	Completed on 8/25/08

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	guidance for initiating and monitoring controlled substance thresholds. Based on our review of the published SOP as well as discussions with DC management and observation of current practices, the following items should be clarified within the SOP: <u>Threshold Excursions, Changes, and Review</u> • A secondary approver for threshold changes should be required if the threshold change is initiated by the DRA. • The SOP documentation should be updated to clarify whether Threshold Change Request forms are required for threshold decreases and existing customers who have been systematically assigned the minimum threshold for a product that has not previously been purchased. • The SOPs should also clarify whether all items listed under Level I review are required to be performed each time a customer meets the threshold and stipulate a timeframe for performing a Level I review after the threshold excursion occurs. • Clear and specific criteria should be established to provide guidance with regard to the nature and types of excursions that require a Level II and Level III review. • The SOP section pertaining to the monthly threshold review by the DRAs should be revised to clarify the frequency with which the review should be performed and the evidence	address or specify all requirements to ensure consistency across all DCs.	procedures to provide consistent guidance to all distribution centers with regard to compliance with the Controlled Substance Monitoring Program.	Don Walker	

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	of review that is required for retention. • The SOP guidance for Level III reviews does not outline who will be responsible for reporting the "suspicious orders" to the DEA. Global CSMP Management procedures - SOP • The SOP does not address the Corporate Records Retention guidelines in place for retaining business records related to CSMP. • The SOP document does not stipulate whether CSMP customer set-up documentation is required for existing customers and for which existing customer segments (ISMC, RNA, MHS) the documentation is required. The SOP should also state which specific documents are required in each customer file for both new and existing customers. • Internal Audit observed that the Lakeland DC had modified the Threshold Change Form to include items such as an original and requested threshold amounts so that the amount of the increase is clearly stated. IA recommends that management consider modifying the Threshold Change Form template to ensure that threshold changes are increased or decreased by the accurate amount. • Based on discussion with senior management, there was no intent for, and little benefit from, the SOP requiring segregation of files for customers exceeding 25,000 doses.				
4	**Supporting Documentation for Existing and New**	**Significance:** High	Recommendation:	Don Walker	Completed on 8/25/08

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	Customers Supporting documentation is not consistently retained for both new and existing McKesson customers. A review of new and existing McKesson customer files for completed sales questionnaires at five DC locations noted the following exceptions: • A review of 132 existing customers determined that 89 customers either did not have sales questionnaires on file or did not have a file containing any documentation. The customer files reviewed included customers from the Retail National Account (RNA), McKesson Health Systems (MHS), and Independent Small Medium Chain (ISMC) segments. • A review of 36 new customers determined that customer files had not been created for 31 of the customers selected.	**Risk:** Failure to maintain records of due diligence may impair McKesson's ability to monitor compliance with the applicable requirements of the CSMP program and demonstrate such compliance upon audit.	Management should clarify the SOP to outline the documentation that is required for existing customers. Training should be provided to DC management to ensure that consistent documentation is retained across the DC network.		
5	**Documentation for Medical-Surgical Customers** Controlled substance orders for Med-Surg customers are currently processed by the Med-Surg Ontario DC and the US Pharma Lakeland DC. Documentation and due diligence for Med-Surg customers who order controlled substances has not been created and retained in compliance with the CSMP SOPs. Additionally, training has not been provided to Med-Surg sales teams and DC management to ensure that consistent documentation is created for all customers.	**Significance:** High **Risk:** Appropriate documentation to provide evidence of customer due diligence may not be on file.	Recommendation: Training should be provided to relevant Med-Surg employees who currently process controlled substance orders to ensure that the required CSMP documentation is utilized and retained. Management should also clarify who will be responsible for compiling and retaining this documentation.	Don Walker	Completed on 8/25/08
6	**Suspicious Order Reporting Format** A formal DEA suspicious order reporting process has not been developed for orders that are escalated to a Level III	**Significance:** Moderate **Risk:** Orders identified as suspicious may not be reported to DEA in a format	Recommendation: Management should develop and implement a template for providing the DEA with Level 3	Don Walker	Completed on 8/25/08

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	review.	acceptable to DEA	suspicious order reporting. The SOP also should be updated to identify the person who is responsible for reporting suspicious orders to the DEA.		
7	**Training Documentation** Formal training policies and training materials have not been implemented to provide an overview of information that was covered, employees who require training, and the frequency with which training should be received. A review of training documentation at five DCs noted the following: • Certifications signed by employees to provide evidence of training provided were not on file at two of the DCs reviewed. • Training certifications were not signed timely (defined as within one week of the training course) for one of the DCs reviewed. • Two employees at one of the DCs reviewed who are responsible for maintaining CSMP documentation had not received CSMP training. • Training for one of the employees who serves as a back-up reviewer/approver for CSMP documentation was not provided timely at one DC. In addition, a formalized training program has not been developed for other key functions such as Sales and Master Data to ensure that all McKesson functions are compliant with the set-up and documentation requirements outlined in the SOPs.	**Significance:** Moderate **Risk:** Employees may not receive adequate training, which could result in improper documentation or monitoring.	Recommendation: Management should formally document a training policy that stipulates who must be trained, what items should be covered during training, and how often training should occur.	Don Walker	Completed on 8/25/08

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
8	**Temporary Threshold Changes** Temporary threshold changes were not always removed timely. A review of the temporary threshold changes at one DC for June noted that the thresholds were not reset until July 11, and the thresholds for July had not been reset as of August 6. Timeliness of temporary threshold removal was not reviewed at the remaining DCs. For threshold changes initiated in August, a system control has been implemented to automatically remove all temporary threshold increases at month end.	**Significance:** Moderate **Risk:** Customers may order unnecessarily large dosages of controlled substances if thresholds are not removed timely.	Recommendation: Management should monitor and scrutinize the system control that removes temporary thresholds to ensure that all temporary threshold changes are automatically removed from the system at the end of each month unless they are designated as permanent.	Keith McIntyre	Completed on 8/25/08
9	**Inappropriate Access to Modify Thresholds** One user, a warehouse supervisor, has inappropriate access to modify threshold values in SAP.	**Significance:** Moderate **Risk:** System thresholds may be adjusted without authorization, resulting in undetected inappropriate controlled substance orders.	Access to the ZS:SD:DEA:RA_MNT role in addition to other roles were removed by SAP Security on 8/4/08 (refer to Remedy incident INC000000171839).	Keith McIntyre	Completed on 8/4/08
10	**FEOP Password Policy** Front-End Order Processing (FEOP) password settings do not adhere to the McKesson Information Security Password Policy (CSP002), which requires the use of a unique password consisting of mixed alpha-numeric characters using both upper and lowercase letters. Currently, passwords consisting of these requirements cannot be enforced. This issue has been previously identified by the Risk & Controls group (RCG) and communicated to the Tandem Support group. Tandem Support is in process of investigating a possible system resolution.	**Significance:** Low **Risk:** Lack of complex password increases the risk of unauthorized access, which may compromise the integrity and availability of the system and data.	Recommendation Have Tandem Support test the new Integrity system to verify if special characters are allowed.	Corinne Bartley	Completed on 9/12/08

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
11	**DC Signage for Controlled Substances** Internal Audit evaluated the process surrounding the isolation of hydrocodone and alprazolam within the two DCs that were subject to suspension of these items. IA reviewed the controls within the cage designed to ensure that the suspended drugs are only shipped to federal government accounts per the terms of the DEA agreement. The Conroe DC has implemented the signage in alprazolam and hydrocodone locations to remind employees that these items should not be shipped to non-federal government accounts. However, this signage is not consistently displayed in all alprazolam and hydrocodone locations to prevent employees from shipping these items to non-federal government accounts if the system fails to re-route or block these orders.	**Significance:** Low **Risk:** Employees may unintentionally ship products containing hydrocodone and alprazolam to non-federal government accounts.	Recommendation: Management should implement signage below all hydrocodone and alprazolam locations to ensure consistency.	Mark Fisher	Completed on 7/18/08
12	**Security of Controlled Substances** At the So Cal DC, security for controlled substances should be improved to ensure that CIIs are appropriately safeguarded. Due to constraints in the DC's system, approximately 20 employees who have access to the cage can also access the vault.	**Significance:** Low **Risk:** Loss or theft of controlled substances.	Recommendation: Management should restrict access to the vault to only those employees who have a legitimate need for access.	Marc Essensa	Completed on 8/25/08
13	**SLA Out of Date** The Tandem service level agreement (SLA0208) refers to the old production and HADR servers, NSK00/NSK01, and not the upgraded servers NSK02/NSK03 that were installed in June 2008.	**Significance:** Low **Risk:** Maintenance and monitoring activities may be delayed or misreported.	A change request was submitted to CIT to update the SLA, which was made on 8/6/08.	Corinne Bartley	Completed on 8/6/08
14	**FEOP Backup Monitoring** FEOP backups manually generated by System Operations are not written into the system back-up log. Therefore,	Significance: Low Risk: Lack of complete back-up logs increases the risk that	The back-up monitoring script for FEOP back-ups generated manually will be updated to write into the system back-up log.	Dean Webber	Completed on 7/22/08

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
	supporting evidence to verify that back-up failures were resolved could not be obtained.	not all failures will be reported and resolved timely.			

Appendix – We observed the following out-of-scope items during our site visits:

#	Issue/Observation	Risk	Action Plan	Action Owner	Action Date
A	**Accuracy of DC Licensure** The DC licensure documentation at Conroe, which is used by employees to determine the states that the DC can ship to, does not accurately reflect the DC's current licensure on file. The spreadsheet stipulates that DC employees can ship to all products to Colorado (including controlled substances). However, a review of the DC licensure determined that the DC did not have a current Wholesaler or Controlled Substance license for Colorado, which is required to ship product to customers (a license is not required for DC transfers).	**Significance:** Moderate **Risk:** Employees may inadvertently ship to customers in Colorado without the required license.	Recommendation: Management should update the DC spreadsheet that is utilized to determine eligibility for customer shipments to prevent items from being shipped directly to customers in Colorado.	Mark Fisher	Completed on 8/11/08
B	**Posting of DC Licensure** At one of the five DCs reviewed, DC licensure was not always posted as required. A review of the population of 53 DC licenses at the DC noted that two were not posted in a conspicuous area as required per DEA regulations.	**Significance:** Low **Risk:** Non-compliance with DEA licensure requirements.	Recommendation: Management should post the two licenses that were not displayed in a prominent location.	Marc Essensa	Completed on 8/25/08